

Notice of Allowability

Application No.

10/531,884

Examiner

Karen Cheng

Applicant(s)

HAIGH ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendments filed 06/21/07.
2. ☒ The allowed claim(s) is/are 1-12, 14-15, 21-24, now renumbered 1-18.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>20070717</u> . |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>04/27/07</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

DETAILED ACTION

Claims 1-24 are currently pending in the instant application. Claims 13 and 16-20 have been cancelled by applicant. The remaining claims have been renumbered as Claims 1-18.

Information Disclosure Statement

Applicant's Information Disclosure Statement filed on 04/27/07 has been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Response to Amendments

Applicant's amendments found in Amendment – After Non-Final Rejection, filed 06/21/2007, have been fully considered and are entered. The objections to claims 1, 3-12 and 21-24 have been withdrawn in view of Applicant's cancellation of non-elected subject matter. The enablement rejection(s) under 35 USC 112, first paragraph of claims 13-15 have been withdrawn in view of Applicant's amendments as well as the following Examiner's Amendment. The ability of compounds such as alpha-interferon and/or ribavirin to treat hepatitis C virus (HCV) infection, along with evidence that inhibition of NS5B RdRp can help treat HCV (see p. 3 of the specification) would allow one of ordinary skill in the art to foresee using the claimed compounds which have inhibitory effects on NS5B HCV polymerase (see p. 102-105 of the specification) in treatment of HCV infection.

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

The application has been amended as follows:

1. Delete from **Claim 1**,

provided that i) E and G are not both hydrogen; and

ii) the compound is other than

4-ethenyl-1-(2-nitrobenzoyl)-2,2-pyrrolidinedicarboxylic acid, diethyl ester;

1-(2-aminobenzoyl)-4-(1-hydroxyethyl)-2,2-pyrrolidinedicarboxylic acid, diethyl ester;

4-(1-hydroxyethyl)-1-(2-nitrobenzoyl)-2,2-pyrrolidinedicarboxylic acid, diethyl ester;

2. Delete from **Claim 14**, "or preventing".

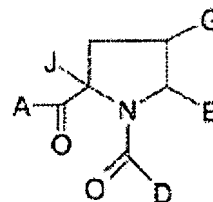
3. Replace the two instances of "Formula (I)" in **Claim 22** with -- Formula (Ia) --.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's Representative Karen Prus on 07/16/07 and 07/18/07.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance.

This invention relates to compounds, pharmaceutical formulations, process of



preparation and method of use of compounds of Formula (Ia) wherein A is hydroxyl, D is aryl, E is heteroaryl or heterocyclyl, G is hydrogen or C₁₋₆ alkyl optionally substituted as defined and J is C₁₋₆ alkyl, heterocyclalkyl, arylalkyl or heteroarylalkyl. The closest prior art has been made of record (see Non-Final Rejection, mailed 04/16/07) and discloses compounds wherein G is halo, substituted

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thio or oxy, but fails to teach or suggest compounds wherein G is C₁₋₆ alkyl substituted as defined of the instant application.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen Cheng
Patent Examiner, AU 1626
18 July 2007

REBECCA ANDERSON
PRIMARY EXAMINER

for

Joseph McKane
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